



APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/403,056	10/13/99	EMBRECHTS	R JAB-1267
PHILIP S. JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK NJ 08933-7003			EXAMINER KISHORE, G ART UNIT 1615 PAPER NUMBER 10

HM12/0626

DATE MAILED: 06/26/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 4-19-01
- ☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-14 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-14 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 8
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

Art Unit: 1615

DETAILED ACTION

The preliminary amendment filed on 10-13-99 is acknowledged.

Claim Rejections - 35 U.S.C. § 112

1. **The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Ketoconazole, does not reasonably provide enablement for antifungal inhibiting ergosterol biosynthesis and as set forth below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Instant specification does not provide adequate support for drugs other than Ketoconazole and formulations other than shampoos. Broad claims must have broad basis of support in the specification; in the absence of such support, claims must be limited to shampoo compositions containing specific components and containing Ketoconazole.**

Body or hair cleansing product ingredients in claim 1 is non-enabling since it is unclear as to what these are.

3. **The following is a quotation of the second paragraph of 35 U.S.C. 112:**

Art Unit: 1615

~~The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.~~

4. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

What is being conveyed by 'synthetic phospholipid' in claim 1? Any phospholipid can be made synthetically. 'Art-known body and hair cleansing product ingredients' in claim 1 is not a positive recitation in a claim. The examiner suggests the incorporation of specific components.

Proper Markush format with the expression 'selected from the group consisting of' and the use of the terms either 'and' OR 'or' only before the last Markush member should be followed in claims 2, 8 and 9.

What is being conveyed by 'one or more of a surfactant' in claim 7?

What do MIPA, DEA and MEA in claims 8 and 9 represent?

Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

Art Unit: :1615

~~(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.~~

6. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2 256

139 of record.

GB discloses emulsions containing terbinafine and a synthetic phospholipid (note the abstract, page 4 and examples). The intended use has no significance in the composition claims.

Claim Rejections - 35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (5,456,851), Mason (5,536,742) individually or in combination, further in combination with Fost (5,688,496).

Liu discloses shampoo formulations containing the various additives and ketonazole as the active ingredient; Liu also discloses that ketonazole is an anti-fungal agent and is

Art Unit: :1615

useful for the treatment of psoriasis and seborrheic dermatitis (note the abstract, columns

1-4, Examples and claims).

Mason similarly discloses shampoo preparations containing ketonazole, econazole or miconazole for the treatment of seborrhoea. Mason notes the association of this disease with yeast (fungus) (note the abstract, columns 1-2 and claims).

What is lacking in the above references is the inclusion of a phospholipid in the shampoo preparations.

Fost (496) while disclosing skin and hair care compositions including shampoos containing synthetic phospholipids teaches the excellent properties of phospholipids such as foaming, viscosity building, wetting, cleansing, detergency and conditioning which makes them very useful (note the abstract, col.1, line 18 through col. 2, line 25, col. 6, line 54 et seq., columns 15-17, examples 16-18 and claims).

Fost (348) while disclosing various personal care products teaches that the synthetic phospholipids have excellent antifungal activity (note the abstract, columns 6-7, examples and claims).

VanMiddlesworth teaches that a synthetic phospholipid of his invention has antifungal activity (note the abstract).

The inclusion of a phospholipid in the shampoo compositions of Liu or Mason would have been obvious to one of ordinary skill in the art since the secondary references

Art Unit: :1615

~~clearly teach the excellent properties of the phospholipids and also their anti-fungal activity.~~

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

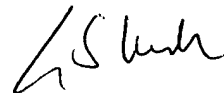
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Art Unit: :1615

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

December 13, 2000